5) 510(k) Summary

This summary of 510(k) information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21CFR807.92.

510(k) Number K092175

FEB 17 2010

Applicant Information

Date Prepared:	**July 16, 2009**
Name and Address:	**FlowCardia, Inc.** **745 N. Pastoria Avenue** **Sunnyvale, CA 94085** **Ph: (408) 617-0352**
Contact Person:	**Dustin Michaels, Vice President of CR/QA/RA** **Ph: (408) 617-0352 x302** **Fax: (408) 617-9198**

Device Information

Classification:	**DQY**
Trade Name:	The CROSSER S6 System
Common Name:	Percutaneous Catheter
Classification Name:	Percutaneous Catheter, 74 DQY / 21 CFR 870.1250

Predicate Devices

The CROSSER LP System manufactured by FlowCardia, Inc. (K080765)
The CROSSER System manufactured by FlowCardia, Inc. (K072776)

Device Description

The CROSSER S6 System consists of a re-usable electronic Generator, Foot Switch, high-frequency Transducer, and single-use CROSSER S6 Catheter.

Each Catheter is connected to the electronic Generator through the Transducer. The Foot Switch is used to activate the system. The Generator and Transducer convert AC power into high-frequency mechanical vibrations which are propagated through a Nitinol core wire to the stainless steel tip of the CROSSER Catheter. The main body of the catheter

is constructed from Pebax and a hydrophilic coating which covers the distal end of the catheter.

Indications For Use

The CROSSER S6 System is indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions. The device is contraindicated for use in carotid arteries.

The CROSSER S6 Catheter is only intended for use with the CROSSER Electronics System. Refer to the CROSSER Electronics System Manual of Operations for proper use.

Technological Characteristics

The FlowCardia CROSSER S6 System is substantially equivalent to the predicate devices. The predicate CROSSER LP Catheter (K080765) and CROSSER S6 Catheter are substantially equivalent with respect to materials, design, construction, and performance. The CROSSER S6 System has the same indication as the predicate CROSSER System (K072776). All CROSSER Systems utilize the same CROSSER Electronics (Generator, transducer, foot switch) for operation.

Physical Test Data

Design analysis, bench, and biocompatibility testing were conducted according to the relevant guidance documents to demonstrate that the FlowCardia CROSSER S6 System met the acceptance criteria and performed similarly to the predicate device. In addition to dimensional verification, the following functional tests were performed: Tensile Strength, Torque Strength, Torqueability, Tip Flexibility, Coating Adherence/Integrity, Biocompatibility, Bench top Simulated Efficiency, Catheter Fatigue Testing, and Shelf Life Testing. Animal studies were conducted with the CROSSER LP predicate device to establish initial safety and performance.

Conclusion

Based upon device physical comparisons, the CROSSER S6 System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

FlowCardia, Inc.
Mr. Dustin Michaels
Vice President, Clinical, Quality & Regulatory Affairs
745 N. Pastoria Ave.
Sunnyvale, CA 94085

Re: K092175
Trade/Device Name: Crosser S6 Catheter System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: December 4, 2009
Received: December 7, 2009

SEP 18 2013

Dear Mr. Michaels:

This letter corrects our substantially equivalent letter of February 17, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K092175

Device Name: **The CROSSER S6 System**

Indications for Use:

The CROSSER S6 System is indicated to facilitate the intra-luminal placement of conventional guidewires beyond peripheral artery chronic total occlusions. The device is contraindicated for use in carotid arteries.

The CROSSER S6 Catheter is only intended for use with the CROSSER Electronics System. Refer to the CROSSER Electronics System Manual of Operations for proper use.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092175